THE ROCKEFELLER UNIVERSITY

pro bono humani generis

1230 YORK AVENUE - NEW YORK, NEW YORK 10021-6399

Joshua Lederberg
UNIVERSITY PROFESSOR

December 12, 1990

To fax to Dr. R. Chanock, 301-496-2443

Dear Bob:

Here are my suggestions for revised wording of the FAS draft (Oct 1990).

There are many useful proposals but their credibility is impaired by careless restrictions on mainstream biomedical research. The whole system will collapse if the reporting is cumbersome and hard to justify.

Page 4, IA, "altered properties that might enhance their usefulness as weapons"...

This is vague. Who knows what might? That could embrace any alteration. And a flat prohibition could interfere with important medical advances - e.g. hyperexpression of a toxin for study of mechanisms of virulence or for production of toxoid.

The important point is that all military research on infectious agents be conducted openly, and "any research that enhances the virulence or transmissibility of an infectious agent should be conducted under stringent conditions of regulation and disclosure and only on a showing that the prospective human benefits exceed any reasonable estimate of the risks". The framework for such oversight already exists in the United States as "recombinant DNA regulation" and is advocated globally in IV-C.

IIIA. "relevant to permitted activities" is not well defined. No matter if it was used in other documents! Any diagnostic and prophylactic research is "relevant" to defense.

Add non-compliant states (under Geneva protocol and BWC) to non signatories.

Clarify whether all medical research collaboration with such states is prescribed.

Would the prohibition apply to citizens and corporations as well as to States Parties (governments)?

IV. A. Domestic Law

Oddly enough, the U.S. law is not in full compliance. Perhaps because the BWC

(sadly) omits "use" (!!), perhaps because this was already forbidden under the Geneva Protocol, the Kohl Bill likewise omits use. It is therefore a poor prototype.

Page 7: D - same problem as IIIA.

What does "jurisdiction or control" mean? Any NIH grant?

"permitted activity" is probably intended to mean "suspect activity that is justified only under the pretense that it is for defense against hostile biological attack." But almost all such research could also be justified as defense against existing disease or what might evolve naturally.

So, "permitted research is either meaningless or all-embracing: that ambiguity is mischievous and could be used to persecute legitimate civilian research. So we need a better way to set the bounds of "forbidden" than by referring to what is "permitted" under another treaty.

D should read that "all infectious disease research should be disclosed if it is operated or contracted by the military establishment. It should also be disclosed by all other individuals or institutions, unless they have an established IRB procedure and and are subject to regulation by the national health and environmental safety authority." Most commercial research is so regulated, and unless it was under military contract would not have to be reported via the national authority. Certain egregiously suspect research, e.g. with variola, or with a very limited number of very high risk agents should also be reportable, and a larger group if they involved larger levels of cultivation than are customary in biomedical research.

Page 9. B - to plant pathogens add other pest control, e.g. myxo in Australia.

Page 10C - add pedagogic to diagnostic and therapeutic - e.g. training of medical and graduate students.

Appendix A, p. 1 - list of controlled agents:

A A1 - "possessed in any quantity" This list is mindlessly borrowed from the history of weaponized agents, regardless of their plausibility. The toxins should have a quantitative threshold.

It is preposterous that these fungi and not others be listed. Puccinia is of very wide natural occurrence. So is Brucella.

A. 2 - should be under quantitative limit for declaration, perhaps another higher one for prohibition.

Appendix A - page 2

Inclusion of Vibrio and Shigella and the plant pathogens as requiring declaration taxes the credibility of the proposal. During the 1st 3 quarters of 1990, there were 200 papers

published with "cholera" in their title; 62 with Brucella; 65 Shigella; 43 tetrodotoxin, 48 Ustilago + Puccinia, almost all from medically or agriculturally beneficent work. Formally reporting all that just dilutes the possibility of real surveillance; is more administrivial red tape; and will generate a lot of pseudo-infractions and thereby domestic as well as international recrimination devoid of content. If there is to be any formal reporting on such agents at all, there should be an exemption for investigators who have published their work with them in generally available books and journals during the previous 3 years. That will identify almost all of the mainstream work in the world, including commercial laboratories, the time interval allowing registration of intellectual property. There might be a case for declaring research that has not been ventilated in that way; though I hate to think that anybody who has grown 10 ml. of stool cultures with some investigative purpose in mind will have to report to an international agency!

A very limited number of agents, should, (by common agreement) be declarable at any level. Perhaps risk group 4 subject to negotiated amendations, and with an exemption for recently published work as indicated above.

Appendix A - page 3

B B1 - these toxins are commercially available in much larger quantities .

Raise the threshold substantially.

Add general point: responsible scientists should be eager to discuss their research or to respond to questions, if any, to explain reasonable delays in publication related to protecting proprietary interests.

Bob -- here are my comments. Please plagiarize them whole, as you wish. But I prefer not to have my own name on them at this stage. You might mention that there was general agreement to these comments from a group of Soviet medical scientists. You could also point out that infectious disease researchers are essentially unrepresented on the core group: if there is a fuss about Alexis, that he has many reservations about the final draft. And do copy to Bob Weinberg.